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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0348]

Index and Copies of Presiding Officer Reports and Commissioner Decisions on the Eligibility of a Clinical Investigator to Continue to Receive Investigational Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the presiding officer summary decisions, presiding officer reports, and the Commissioner of Food and Drugs (the Commissioner) decisions that are issued concerning a regulatory hearing on the proposed disqualification of a clinical investigator from eligibility to continue to receive investigational products for use in clinical investigations. These reports and decisions and an index are available at the FDA Internet site.

ADDRESSES: Copies of an index to presiding officer summary decisions, presiding officer reports, and Commissioner decisions, as well as the reports and decisions themselves, may be obtained from the Freedom of Information Office home page at http://www.fda.gov/foi/clinicaldis.

Copies of the index and reports and decisions are also available at the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of the Ombudsman (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

SUPPLEMENTARY INFORMATION: FDA regulates scientific studies, known as clinical investigations, designed to test the safety and effectiveness of investigational human and animal drugs, biological products, and medical devices. The data from these clinical investigations may be used as the

basis of applications to FDA for approval to market the investigational products. The clinical investigators who conduct clinical trials must comply with FDA's regulations that govern clinical investigations. FDA may seek to disqualify a clinical investigator if the agency has information indicating that the investigator has repeatedly or deliberately failed to comply with the requirements of the regulations for conducting clinical investigations, or repeatedly or deliberately submitted false data to the FDA or the study's sponsor. If the Commissioner makes this determination, the Commissioner will notify the investigator and the sponsor of any investigation, in which the investigator has been named as a participant, that the investigator is not entitled to receive investigational drugs.

The criteria for disqualification are set forth in FDA's regulations. For clinical investigations involving human drugs and biologic products, the applicable regulation is found at 21 CFR 312.70. For clinical investigations involving medical devices, the applicable regulation is found at 21 CFR 812.119. For clinical investigations involving investigational animal drugs, the applicable regulation is found at 21 CFR 511.1.

The disqualification process is initiated when FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, or Center for Veterinary Medicine sends the investigator a written notice of the matter complained of, and offers the investigator an opportunity to explain in writing or, at the option of the investigator, at an informal conference. If the Center does not find the investigator's explanation to be acceptable, the agency will send the investigator a notice of opportunity for a hearing. If a regulatory hearing is held, it will be conducted under part 16 (21 CFR part 16). Under part 16, if a clinical investigator requests a hearing, a presiding officer is appointed to hear the case. A request for a hearing may be denied if the Commissioner or his or her delegate determines that there is no genuine and substantial issue of fact to justify a hearing. A written notice of this determination will be given to the parties. In addition, the presiding officer may issue a

summary decision on any issue in the hearing if the presiding officer determines that there is no genuine and substantial issue of fact respecting that issue.

After a hearing is conducted, the presiding officer, under § 16.60, prepares a written report of the hearing, including a recommended decision with a statement of the reasons, on the proposed disqualification. The written report will include a recommended decision with a statement of reasons, unless the Commissioner directs otherwise. The presiding officer's report is one component of the administrative record of the hearing. Based on the administrative record, the Commissioner issues a written decision on the question of whether the investigator is entitled to receive investigational products. If the Commissioner finds that the clinical investigator repeatedly or deliberately failed to comply with agency regulations, or repeatedly or deliberately submitted false information to FDA or the sponsor, the investigator may be disqualified from receiving investigational products.

Disqualification hearings are informal, and presiding officer summary decisions, presiding officer reports, and Commissioner decisions are not published in the **Federal Register**; they have been made publicly available to parties that request regulatory hearings on clinical investigator disqualifications. They are also publicly available under the Freedom of Information Act. The purpose of this notice is to announce that an index to, and copies of, presiding officer summary decisions, presiding officer reports, and Commissioner decisions on clinical investigator

disqualification matters are now available on FDA's Internet site. These records are also available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/21/01

August 21, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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